K002534

OCT 1 8 2000

510(k) SUMMARY
[21 CFR §807.87(h)]

SUBMITTER'S INFORMATION [21 CFR §807.92(a)(1)]

Manufacturer	Eupalamus, LLC
Company Representative	H. Stephen Cookston
Authorized Representative	Anne Lauritzen
Address	3411 Mandeville Canyon Road Brentwood, CA 90049
Telephone	(310) 471-6289
Fax	(310) 471- 4685

Date Summary Prepared: August 15, 2000

NAME OF THE DEVICE [21 CFR §807.92(a)(2)]

Common Name: Steerable Stylet

Brand Name: Eupalamus Deflectable Stylet

Classification Name: Catheter Stylet (21 CFR §870.1380)

PREDICATE DEVICE [21 CFR §807.92(a)(3)]

Common Name: Steerable Stylet

Brand Name: Placer™ Model 6232

Manufacturer: Medtronic

Classification: Catheter Stylet (21 CFR §870.1380)

File # K000955

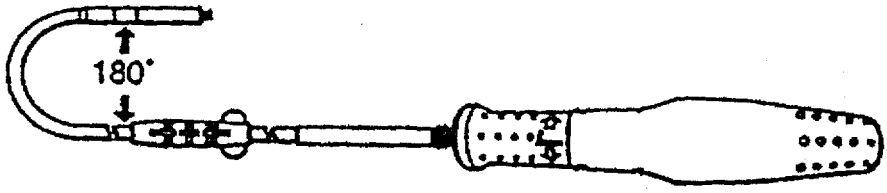
DEVICE DESCRIPTION [21 CFR §807.92(a)(4)]

The Eupalamus Deflectable Stylet is a Class II device that assists in the procedure to implant pacemaker leads. It is a sterile, single use device.

The device is designed for one-hand operation. It is comprised of predominantly two components, the stylet wire and the stylet handle. The stylet handle is made of various plastic components. The stylet wire is made of stainless steel.

The Deflectable Stylet is a 0.015 inch nominal diameter stylet which can take a J-shape up to 180° while inside a pacemaker lead. The user does not have to remove the stylet from the lead in order to change the shape.

The Stylet handle contains a "spinner" mechanism that controls the shaping of the stylet. When "spinner" is turned to the right, the stylet assumes a J-shape. When turned to the left, the stylet is straightened. The handle also has the ability to allow the user to move the stylet into a J-shape by pushing the spinner portion on the handle forward.



STATEMENT OF INTENDED USE [21 CFR §807.92(a)(5)]

INTENDED USE

When inserted into the lumen of a lead, the Eupalamus Deflectable Stylet Model 01545 assists in implantation of straight Medtronic right atrial and right ventricular transvenous leads which accept a 0.016" stylet.

TECHNOLOGICAL CHARACTERISTICS [21 CFR §807.92(a)(6)]

SIMILARITIES AND DIFFERENCES

The intended use of the Eupalamus Deflectable Stylet is similar to the Medtronic Placer™ Model 6232 Steerable Stylet as reflected by the labeling of both devices. Both devices are to be inserted into the lumen of pacemaker leads to assist in implantation of the leads. The target patient population of both devices are the same, as well as the anatomical sites in which the devices will be used. Both devices are intended to be used by prescription only in a hospital setting. The Eupalamus Deflectable Stylet has the same interaction with patients, users and the hospital environment, as well as other devices as the Medtronic Placer™ Model 6232 Steerable Stylet.

The Eupalamus Deflectable Stylet is also similar to the Medtronic Placer™ Model 6232 Steerable Stylet in most of its technological characteristics. For instance, it is a manual device of the same design and undergoes similar qualification procedures. It is tested to the same release parameters and requirements in order to assure equivalent performance. It is built with the same materials, therefore the biocompatibility of the devices are equivalent. In fact, in most cases the Eupalamus Deflectable Stylet materials and components are purchased from the exact same suppliers as those of the Medtronic Placer™ Model 6232 Steerable Stylet and in accordance with identical specifications.

Two differences exist between the devices regarding technological characteristics. The first is the diameter of the stylets. The second technological difference between the devices is the fact that they will be built at different manufacturing facilities and packaged and sterilized by different contracted companies.

COMPARISON TABLE

AREAS FOR COMPARISON (FDA 95-4158 § 9)	Eupalamus Deflectable Stylet	Medtronic Placer™ Model 6232 Steerable Stylet
Indications for Use	When inserted into the lumen of a lead, the Eupalamus Deflectable Stylet Model 01545 assists in implantation of straight Medtronic right atrial and right ventricular transvenous leads which accept a 0.016" stylet.	When inserted into the lumen of a lead, the Placer Model 6232 Steerable Stylet assists in implantation of straight Medtronic right atrial and right ventricular transvenous leads which accept a 0.016" stylet.
Target Population	Patients requiring pacemaker lead implantation	Patients requiring pacemaker lead implantation
Design	Built to Medtronic Placer specification excepting stylet diameter of 0.015"	Built to Medtronic Placer specification (stylet diameter of 0.016")
Materials	Wire: Stainless Steel Handle: Plastic/Polycarbonate	Wire: Stainless Steel Handle: Plastic/Polycarbonate
Performance	Qualification and testing protocol to Medtronic specification	Qualification and testing protocol to Medtronic specification
Sterility	AAMI/ISO TIR No. 15844:1998	ANSI/ AAMI/ISO 11137-1994
Biocompatibility	No patient contact	No patient contact
Mechanical Safety	Risk Analysis and Qualification testing performed	Risk Analysis and Qualification testing performed
Chemical Safety	N/A: Device does not contain chemicals.	N/A: Device does not contain chemicals.
Anatomical Sites	Used with Right atrial and right ventricular transvenous pacemaker leads	Used with Right atrial and right ventricular transvenous pacemaker leads
Human Factors	Pacemaker Implantation Procedure	Pacemaker Implantation Procedure
Energy Used/Delivered	Manual Device	Manual Device
Compatibility/Environment	Sterile, Single Use, Disposable	Sterile, Single Use, Disposable
Compatibility/Other Devices	Tested with Medtronic Lead	Tested with Medtronic Lead
Where Used	Prescription Device: Hospital	Prescription Device: Hospital
Standards Met	QSR/ISO	QSR/ISO
Electrical Safety	N/A: Mechanical Device	N/A: Mechanical Device
Thermal Safety	N/A: Mechanical Device	N/A: Mechanical Device
Radiation Safety	N/A: Mechanical Device	N/A: Mechanical Device

PERFORMANCE DATA [21 CFR §807.92(b)]

Performance data for the Eupalamus Deflectable Stylet has not been submitted with this Premarket Notification.

Pre-clinical Testing

Eupalamus will perform a vigorous initial process qualification protocol, as well as follow a recognized standard (AAMI/ISO TIR No. 15844:1998) for the on-going validation of the Deflectable Stylet sterilization process. A description of the sterility methods to be used and validation performed is outlined in the "Additional Information" section of this submission.

Initial qualification of Eupalamus Deflectable Stylet to assure it meets specifications as well as performance criteria will include visual inspection, critical dimension inspection, mechanical inspection, joint tensile strength testing and lead compatibility testing. These qualification test protocols will then be incorporated into the Quality Assurance Program for production and market release of the device.

The pre-clinical testing described above will demonstrate the device is safe, since the initial sterility validation and on-going validation will be performed to a recognized industry standard. The pre-clinical testing will also demonstrate that the device is effective because the specifications and performance criteria of the device are equivalent to those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2000

Ms. Anne Lauritzen
Regulatory Affairs Director
Eupalamus, LLC
3411 Mandeville Canyon Road
Brentwood, CA 90049

Re: K002534
Trade Name: Eupalamus Deflectable Sytlet, Model 01545
Regulatory Class: II (two)
Product Code: 74 DRB
Dated: August 15, 2000
Received: August 16, 2000

Dear Ms. Lauritzen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002534

Device Name: Eupalamus Deflectable Stylet, Model 01545

Indications For Use:

When inserted into the lumen of a lead, the Eupalamus Deflectable Stylet Model 01545 assists in implantation of straight Medtronic right atrial and right ventricular transvenous leads which accept a 0.016" stylet.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002534

(Optional Format 3-10-98)

Prescription Use Only